UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION	No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: Zhejiang Menovo Pharmaceutical Co., Ltd., 8 Jingshisan Rd, Shangyu District, Shaoxing, Zhejiang, China.

Production: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Place:	Date and Time:
GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55401	November 15, 2020

Inspection of Premises: YOU ARE COMMANDED to permit entry onto the designated premises, land or other property possessed or controlled by you at the time, date and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property of any designated object or operation on it.

Place:	Date and Time:

The following provisions of Fed. R. Civ. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to you duty to respond to this subpoena and the potential consequences of not doing so.

Date: _____

CLERK OF COURT

OR

_____ _____

Signature of Clerk or Deputy Clerk *Attorney's signature*

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, mjgoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

RELEVANT PORTIONS OF FED. R. CIV. P. 45

(c) PLACE OF COMPLIANCE.

(1) *For a Trial, Hearing, or Deposition.* A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

(A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or

(B) within the state where the person resides, is employed, or regularly transacts business in person, if the person

(i) is a party or a party's officer; or

(ii) is commanded to attend a trial and would not incur substantial expense.

(2) *For Other Discovery.* A subpoena may command:

(A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and

(B) inspection of premises at the premises to be inspected.

(d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.

(1) *Avoiding Undue Burden or Expense; Sanctions.* A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) *Command to Produce Materials or Permit Inspection.*

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) *Quashing or Modifying a Subpoena.*

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(e) DUTIES IN RESPONDING TO A SUBPOENA.

(1) *Producing Documents or Electronically Stored Information.* These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) *Claiming Privilege or Protection.*

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

(i) expressly make the claim; and

(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) CONTEMPT. The court for the district where compliance is required — and also, after a motion is transferred, the issuing court — may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

SCHEDULE A

A. Definitions

1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).

2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.

3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.

4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.

5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

6. "FDA" means the United States Food & Drug Administration.

7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.

8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.

9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.

10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.

11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.

12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).

13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

DOCUMENT TO BE PRODUCED

Corporate Organization

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

Contracts

1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.
3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

Communications with Relevant Parties

1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
    a. Date
    b. Recipients and/or Senders of the Communication
    c. General Subject Matter
    d. Basis of Privilege

ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

Nitrosamine Contamination

1. All communications between you and any Defendant relating to nitrosamines.
2. All communications between you and any Defendant concerning any toxicology assessment.
3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
6. All draft reports edited by you for comment and provided to any Defendant.
7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
10. All documents or communications relating to nitrosamine testing of any drug.

Recall-Related Documents

1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

Quarantine and/or Destruction

1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
5. All destruction certifications created related to any ARB products or API.

Communications with the FDA

1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

Testing Data

1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

Toxicology Assessments

1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION	No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: aaiPharma Inc., 2320 Scientific Park Drive Wilmington, NC 28405.

Production: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Place:	Date and Time:
GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55401	November 15, 2020

Inspection of Premises: YOU ARE COMMANDED to permit entry onto the designated premises, land or other property possessed or controlled by you at the time, date and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property of any designated object or operation on it.

Place:	Date and Time:

The following provisions of Fed. R. Civ. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to you duty to respond to this subpoena and the potential consequences of not doing so.

Date: 10/15/2020

CLERK OF COURT

OR

_____ /s/ Marlene J. Goldenberg

Signature of Clerk or Deputy Clerk *Attorney's signature*

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:
Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, mjgoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

RELEVANT PORTIONS OF FED. R. CIV. P. 45

(c) PLACE OF COMPLIANCE.

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(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

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(i) disclosing a trade secret or other confidential research, development, or commercial information; or

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3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.

4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.

5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

6. "FDA" means the United States Food & Drug Administration.

7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.

8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.

9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.

10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.

11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.

12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).

13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

DOCUMENT TO BE PRODUCED

Corporate Organization

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

Contracts

1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.
3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

Communications with Relevant Parties

1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
    a. Date
    b. Recipients and/or Senders of the Communication
    c. General Subject Matter
    d. Basis of Privilege

ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

Nitrosamine Contamination

1. All communications between you and any Defendant relating to nitrosamines.
2. All communications between you and any Defendant concerning any toxicology assessment.
3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
6. All draft reports edited by you for comment and provided to any Defendant.
7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
10. All documents or communications relating to nitrosamine testing of any drug.

Recall-Related Documents

1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

Quarantine and/or Destruction

1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
5. All destruction certifications created related to any ARB products or API.

Communications with the FDA

1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

Testing Data

1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

Toxicology Assessments

1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION	No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: International Trading Pharmaceuticals Laboratories, Inc., 470 Chamberlain Avenue, Suite 12, Paterson, NJ, 07522.

Production: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Place:	Date and Time:
GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55401	November 15, 2020

Inspection of Premises: YOU ARE COMMANDED to permit entry onto the designated premises, land or other property possessed or controlled by you at the time, date and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property of any designated object or operation on it.

Place:	Date and Time:

The following provisions of Fed. R. Civ. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to you duty to respond to this subpoena and the potential consequences of not doing so.

Date: 10/15/2020

CLERK OF COURT

OR

_____ /s/ Marlene J. Goldenberg

Signature of Clerk or Deputy Clerk *Attorney's signature*

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:
Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, mjgoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

RELEVANT PORTIONS OF FED. R. CIV. P. 45

(c) PLACE OF COMPLIANCE.

(1) *For a Trial, Hearing, or Deposition.* A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

(A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or

(B) within the state where the person resides, is employed, or regularly transacts business in person, if the person

(i) is a party or a party's officer; or

(ii) is commanded to attend a trial and would not incur substantial expense.

(2) *For Other Discovery.* A subpoena may command:

(A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and

(B) inspection of premises at the premises to be inspected.

(d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.

(1) *Avoiding Undue Burden or Expense; Sanctions.* A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) *Command to Produce Materials or Permit Inspection.*

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) *Quashing or Modifying a Subpoena.*

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(e) DUTIES IN RESPONDING TO A SUBPOENA.

(1) *Producing Documents or Electronically Stored Information.* These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) *Claiming Privilege or Protection.*

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

(i) expressly make the claim; and

(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) CONTEMPT. The court for the district where compliance is required — and also, after a motion is transferred, the issuing court — may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

SCHEDULE A

A. Definitions

1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).

2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.

3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.

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Communications with the FDA

1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

Testing Data

1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

Toxicology Assessments

1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION	No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: Prevalere Life Sciences Inc., 8282 Halsey Road, Whitesboro, NY 13492.

Production: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Place:	Date and Time:
GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55401	November 15, 2020

Inspection of Premises: YOU ARE COMMANDED to permit entry onto the designated premises, land or other property possessed or controlled by you at the time, date and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property of any designated object or operation on it.

Place:	Date and Time:

The following provisions of Fed. R. Civ. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to you duty to respond to this subpoena and the potential consequences of not doing so.

Date: 10/15/2020

CLERK OF COURT

OR

_____ /s/ Marlene J. Goldenberg

Signature of Clerk or Deputy Clerk *Attorney's signature*

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:
Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, mjgoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

RELEVANT PORTIONS OF FED. R. CIV. P. 45

(c) PLACE OF COMPLIANCE.

(1) *For a Trial, Hearing, or Deposition.* A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

(A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or

(B) within the state where the person resides, is employed, or regularly transacts business in person, if the person

(i) is a party or a party's officer; or

(ii) is commanded to attend a trial and would not incur substantial expense.

(2) *For Other Discovery.* A subpoena may command:

(A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and

(B) inspection of premises at the premises to be inspected.

(d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.

(1) *Avoiding Undue Burden or Expense; Sanctions.* A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) *Command to Produce Materials or Permit Inspection.*

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) *Quashing or Modifying a Subpoena.*

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(e) DUTIES IN RESPONDING TO A SUBPOENA.

(1) *Producing Documents or Electronically Stored Information.* These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) *Claiming Privilege or Protection.*

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

(i) expressly make the claim; and

(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) CONTEMPT. The court for the district where compliance is required — and also, after a motion is transferred, the issuing court — may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

SCHEDULE A

A. Definitions

1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).

2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.

3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.

4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.

5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

6. "FDA" means the United States Food & Drug Administration.

7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.

8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.

9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.

10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.

11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.

12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).

13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

DOCUMENT TO BE PRODUCED

Corporate Organization

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

Contracts

1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.
3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

Communications with Relevant Parties

1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
    a. Date
    b. Recipients and/or Senders of the Communication
    c. General Subject Matter
    d. Basis of Privilege

ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

Nitrosamine Contamination

1. All communications between you and any Defendant relating to nitrosamines.
2. All communications between you and any Defendant concerning any toxicology assessment.
3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
6. All draft reports edited by you for comment and provided to any Defendant.
7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
10. All documents or communications relating to nitrosamine testing of any drug.

Recall-Related Documents

1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

Quarantine and/or Destruction

1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
5. All destruction certifications created related to any ARB products or API.

Communications with the FDA

1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

Testing Data

1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

Toxicology Assessments

1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION	No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: Jubilant Generics, 790 Township Line Road, Suite 175, Yardley, PA 19067.

Production: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Place:	Date and Time:
GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55401	November 15, 2020

Inspection of Premises: YOU ARE COMMANDED to permit entry onto the designated premises, land or other property possessed or controlled by you at the time, date and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property of any designated object or operation on it.

Place:	Date and Time:

The following provisions of Fed. R. Civ. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to you duty to respond to this subpoena and the potential consequences of not doing so.

Date: 10/15/2020

CLERK OF COURT

OR

_____ /s/ Marlene J. Goldenberg

Signature of Clerk or Deputy Clerk *Attorney's signature*

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:
Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, mjgoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

RELEVANT PORTIONS OF FED. R. CIV. P. 45

(c) PLACE OF COMPLIANCE.

(1) *For a Trial, Hearing, or Deposition.* A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

(A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or

(B) within the state where the person resides, is employed, or regularly transacts business in person, if the person

(i) is a party or a party's officer; or

(ii) is commanded to attend a trial and would not incur substantial expense.

(2) *For Other Discovery.* A subpoena may command:

(A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and

(B) inspection of premises at the premises to be inspected.

(d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.

(1) *Avoiding Undue Burden or Expense; Sanctions.* A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) *Command to Produce Materials or Permit Inspection.*

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) *Quashing or Modifying a Subpoena.*

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(e) DUTIES IN RESPONDING TO A SUBPOENA.

(1) *Producing Documents or Electronically Stored Information.* These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) *Claiming Privilege or Protection.*

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

(i) expressly make the claim; and

(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) CONTEMPT. The court for the district where compliance is required — and also, after a motion is transferred, the issuing court — may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

SCHEDULE A

A. Definitions

1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).

2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.

3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.

4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.

5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

6. "FDA" means the United States Food & Drug Administration.

7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.

8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.

9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.

10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.

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13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

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14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

DOCUMENT TO BE PRODUCED

Corporate Organization

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

Contracts

1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.
3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

Communications with Relevant Parties

1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
    a. Date
    b. Recipients and/or Senders of the Communication
    c. General Subject Matter
    d. Basis of Privilege

ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

Nitrosamine Contamination

1. All communications between you and any Defendant relating to nitrosamines.
2. All communications between you and any Defendant concerning any toxicology assessment.
3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
6. All draft reports edited by you for comment and provided to any Defendant.
7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
10. All documents or communications relating to nitrosamine testing of any drug.

Recall-Related Documents

1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

Quarantine and/or Destruction

1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
5. All destruction certifications created related to any ARB products or API.

Communications with the FDA

1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

Testing Data

1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

Toxicology Assessments

1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION	No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: Integrated Analytical Laboratories, LLC, 273 Franklin Road, Randolph, NJ 07869.

Production: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Place:	Date and Time:
GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55401	November 15, 2020

Inspection of Premises: YOU ARE COMMANDED to permit entry onto the designated premises, land or other property possessed or controlled by you at the time, date and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property of any designated object or operation on it.

Place:	Date and Time:

The following provisions of Fed. R. Civ. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to you duty to respond to this subpoena and the potential consequences of not doing so.

Date: 10/15/2020

CLERK OF COURT

OR

_____ /s/ Marlene J. Goldenberg

Signature of Clerk or Deputy Clerk *Attorney's signature*

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:
Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, mjgoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

RELEVANT PORTIONS OF FED. R. CIV. P. 45

(c) PLACE OF COMPLIANCE.

(1) *For a Trial, Hearing, or Deposition.* A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

(A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or

(B) within the state where the person resides, is employed, or regularly transacts business in person, if the person

(i) is a party or a party's officer; or

(ii) is commanded to attend a trial and would not incur substantial expense.

(2) *For Other Discovery.* A subpoena may command:

(A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and

(B) inspection of premises at the premises to be inspected.

(d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.

(1) *Avoiding Undue Burden or Expense; Sanctions.* A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) *Command to Produce Materials or Permit Inspection.*

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) *Quashing or Modifying a Subpoena.*

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(e) DUTIES IN RESPONDING TO A SUBPOENA.

(1) *Producing Documents or Electronically Stored Information.* These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

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(i) expressly make the claim; and

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2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
    a. Date
    b. Recipients and/or Senders of the Communication
    c. General Subject Matter
    d. Basis of Privilege

ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

Nitrosamine Contamination

1. All communications between you and any Defendant relating to nitrosamines.
2. All communications between you and any Defendant concerning any toxicology assessment.
3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
6. All draft reports edited by you for comment and provided to any Defendant.
7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
10. All documents or communications relating to nitrosamine testing of any drug.

Recall-Related Documents

1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

Quarantine and/or Destruction

1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
5. All destruction certifications created related to any ARB products or API.

Communications with the FDA

1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

Testing Data

1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

Toxicology Assessments

1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION	No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: Catalent, Inc., 14 Schoolhouse Road Somerset, NJ 08873.

Production: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Place:	Date and Time:
GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55401	November 15, 2020

Inspection of Premises: YOU ARE COMMANDED to permit entry onto the designated premises, land or other property possessed or controlled by you at the time, date and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property of any designated object or operation on it.

Place:	Date and Time:

The following provisions of Fed. R. Civ. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to you duty to respond to this subpoena and the potential consequences of not doing so.

Date: 10/15/2020

CLERK OF COURT

OR

_____ /s/ Marlene J. Goldenberg

Signature of Clerk or Deputy Clerk *Attorney's signature*

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:
Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, mjgoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

RELEVANT PORTIONS OF FED. R. CIV. P. 45

(c) PLACE OF COMPLIANCE.

(1) *For a Trial, Hearing, or Deposition.* A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

(A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or

(B) within the state where the person resides, is employed, or regularly transacts business in person, if the person

(i) is a party or a party's officer; or

(ii) is commanded to attend a trial and would not incur substantial expense.

(2) *For Other Discovery.* A subpoena may command:

(A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and

(B) inspection of premises at the premises to be inspected.

(d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.

(1) *Avoiding Undue Burden or Expense; Sanctions.* A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) *Command to Produce Materials or Permit Inspection.*

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) *Quashing or Modifying a Subpoena.*

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(e) DUTIES IN RESPONDING TO A SUBPOENA.

(1) *Producing Documents or Electronically Stored Information.* These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) *Claiming Privilege or Protection.*

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

(i) expressly make the claim; and

(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) CONTEMPT. The court for the district where compliance is required — and also, after a motion is transferred, the issuing court — may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

SCHEDULE A

A. Definitions

1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).

2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.

3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.

4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.

5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

6. "FDA" means the United States Food & Drug Administration.

7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.

8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.

9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.

10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.

11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.

12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).

13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

DOCUMENT TO BE PRODUCED

Corporate Organization

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

Contracts

1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.
3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

Communications with Relevant Parties

1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
    a. Date
    b. Recipients and/or Senders of the Communication
    c. General Subject Matter
    d. Basis of Privilege

ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

Nitrosamine Contamination

1. All communications between you and any Defendant relating to nitrosamines.
2. All communications between you and any Defendant concerning any toxicology assessment.
3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
6. All draft reports edited by you for comment and provided to any Defendant.
7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
10. All documents or communications relating to nitrosamine testing of any drug.

Recall-Related Documents

1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

Quarantine and/or Destruction

1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
5. All destruction certifications created related to any ARB products or API.

Communications with the FDA

1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

Testing Data

1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

Toxicology Assessments

1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION	No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: SGS US Testing Co. Inc., 201 Route 17, North Rutherford, NJ 07070.

Production: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Place:	Date and Time:
GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55401	November 15, 2020

Inspection of Premises: YOU ARE COMMANDED to permit entry onto the designated premises, land or other property possessed or controlled by you at the time, date and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property of any designated object or operation on it.

Place:	Date and Time:

The following provisions of Fed. R. Civ. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to you duty to respond to this subpoena and the potential consequences of not doing so.

Date: 10/15/2020

CLERK OF COURT

OR

_____ /s/ Marlene J. Goldenberg

Signature of Clerk or Deputy Clerk *Attorney's signature*

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:
Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, mjgoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

RELEVANT PORTIONS OF FED. R. CIV. P. 45

(c) PLACE OF COMPLIANCE.

(1) *For a Trial, Hearing, or Deposition.* A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

(A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or

(B) within the state where the person resides, is employed, or regularly transacts business in person, if the person

(i) is a party or a party's officer; or

(ii) is commanded to attend a trial and would not incur substantial expense.

(2) *For Other Discovery.* A subpoena may command:

(A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and

(B) inspection of premises at the premises to be inspected.

(d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.

(1) *Avoiding Undue Burden or Expense; Sanctions.* A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) *Command to Produce Materials or Permit Inspection.*

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) *Quashing or Modifying a Subpoena.*

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(e) DUTIES IN RESPONDING TO A SUBPOENA.

(1) *Producing Documents or Electronically Stored Information.* These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) *Claiming Privilege or Protection.*

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

(i) expressly make the claim; and

(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) CONTEMPT. The court for the district where compliance is required — and also, after a motion is transferred, the issuing court — may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

SCHEDULE A

A. Definitions

1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).

2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.

3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.

4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.

5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

6. "FDA" means the United States Food & Drug Administration.

7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.

8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.

9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.

10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.

11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.

12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).

13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

DOCUMENT TO BE PRODUCED

Corporate Organization

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

Contracts

1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.
3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

Communications with Relevant Parties

1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
    a. Date
    b. Recipients and/or Senders of the Communication
    c. General Subject Matter
    d. Basis of Privilege

ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

Nitrosamine Contamination

1. All communications between you and any Defendant relating to nitrosamines.
2. All communications between you and any Defendant concerning any toxicology assessment.
3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
6. All draft reports edited by you for comment and provided to any Defendant.
7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
10. All documents or communications relating to nitrosamine testing of any drug.

Recall-Related Documents

1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

Quarantine and/or Destruction

1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
5. All destruction certifications created related to any ARB products or API.

Communications with the FDA

1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

Testing Data

1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

Toxicology Assessments

1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION	No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: WRB Corp., 475 Steamboat Road, Greenwich, CT 06830.

Production: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Place:	Date and Time:
GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55401	November 15, 2020

Inspection of Premises: YOU ARE COMMANDED to permit entry onto the designated premises, land or other property possessed or controlled by you at the time, date and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property of any designated object or operation on it.

Place:	Date and Time:

The following provisions of Fed. R. Civ. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to you duty to respond to this subpoena and the potential consequences of not doing so.

Date: 10/15/2020

CLERK OF COURT

OR

_____ /s/ Marlene J. Goldenberg

Signature of Clerk or Deputy Clerk *Attorney's signature*

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:
Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, mjgoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

RELEVANT PORTIONS OF FED. R. CIV. P. 45

(c) PLACE OF COMPLIANCE.

(1) *For a Trial, Hearing, or Deposition.* A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

(A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or

(B) within the state where the person resides, is employed, or regularly transacts business in person, if the person

(i) is a party or a party's officer; or

(ii) is commanded to attend a trial and would not incur substantial expense.

(2) *For Other Discovery.* A subpoena may command:

(A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and

(B) inspection of premises at the premises to be inspected.

(d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.

(1) *Avoiding Undue Burden or Expense; Sanctions.* A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) *Command to Produce Materials or Permit Inspection.*

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

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13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

DOCUMENT TO BE PRODUCED

Corporate Organization

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

Contracts

1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.
3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

Communications with Relevant Parties

1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
    a. Date
    b. Recipients and/or Senders of the Communication
    c. General Subject Matter
    d. Basis of Privilege

ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

Nitrosamine Contamination

1. All communications between you and any Defendant relating to nitrosamines.
2. All communications between you and any Defendant concerning any toxicology assessment.
3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
6. All draft reports edited by you for comment and provided to any Defendant.
7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
10. All documents or communications relating to nitrosamine testing of any drug.

Recall-Related Documents

1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

Quarantine and/or Destruction

1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
5. All destruction certifications created related to any ARB products or API.

Communications with the FDA

1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

Testing Data

1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

Toxicology Assessments

1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION	No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: Gibralter Laboratories, Inc., 122 Fairfield Rd., Fairfield, NJ 07004.

Production: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Place:	Date and Time:
GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55401	November 15, 2020

Inspection of Premises: YOU ARE COMMANDED to permit entry onto the designated premises, land or other property possessed or controlled by you at the time, date and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property of any designated object or operation on it.

Place:	Date and Time:

The following provisions of Fed. R. Civ. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to you duty to respond to this subpoena and the potential consequences of not doing so.

Date: 10/15/2020

CLERK OF COURT

OR

_____ /s/ Marlene J. Goldenberg

Signature of Clerk or Deputy Clerk *Attorney's signature*

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:
Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, mjgoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

RELEVANT PORTIONS OF FED. R. CIV. P. 45

(c) PLACE OF COMPLIANCE.

(1) *For a Trial, Hearing, or Deposition.* A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

(A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or

(B) within the state where the person resides, is employed, or regularly transacts business in person, if the person

(i) is a party or a party's officer; or

(ii) is commanded to attend a trial and would not incur substantial expense.

(2) *For Other Discovery.* A subpoena may command:

(A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and

(B) inspection of premises at the premises to be inspected.

(d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.

(1) *Avoiding Undue Burden or Expense; Sanctions.* A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) *Command to Produce Materials or Permit Inspection.*

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) *Quashing or Modifying a Subpoena.*

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(e) DUTIES IN RESPONDING TO A SUBPOENA.

(1) *Producing Documents or Electronically Stored Information.* These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) *Claiming Privilege or Protection.*

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

(i) expressly make the claim; and

(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) CONTEMPT. The court for the district where compliance is required — and also, after a motion is transferred, the issuing court — may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

SCHEDULE A

A. Definitions

1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).

2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.

3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.

4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.

5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

6. "FDA" means the United States Food & Drug Administration.

7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.

8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.

9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.

10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.

11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.

12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).

13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

DOCUMENT TO BE PRODUCED

Corporate Organization

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

Contracts

1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.
3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

Communications with Relevant Parties

1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
    a. Date
    b. Recipients and/or Senders of the Communication
    c. General Subject Matter
    d. Basis of Privilege

ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

Nitrosamine Contamination

1. All communications between you and any Defendant relating to nitrosamines.
2. All communications between you and any Defendant concerning any toxicology assessment.
3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
6. All draft reports edited by you for comment and provided to any Defendant.
7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
10. All documents or communications relating to nitrosamine testing of any drug.

Recall-Related Documents

1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

Quarantine and/or Destruction

1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
5. All destruction certifications created related to any ARB products or API.

Communications with the FDA

1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

Testing Data

1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

Toxicology Assessments

1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION	No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: Southern Testing & Research Laboratories, 3809 Airport Drive, Wilson, NC 27896.

Production: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Place:	Date and Time:
GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55401	November 15, 2020

Inspection of Premises: YOU ARE COMMANDED to permit entry onto the designated premises, land or other property possessed or controlled by you at the time, date and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property of any designated object or operation on it.

Place:	Date and Time:

The following provisions of Fed. R. Civ. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to you duty to respond to this subpoena and the potential consequences of not doing so.

Date: 10/15/2020

CLERK OF COURT

OR

_____ /s/ Marlene J. Goldenberg

Signature of Clerk or Deputy Clerk *Attorney's signature*

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:
Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, mjgoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

RELEVANT PORTIONS OF FED. R. CIV. P. 45

(c) PLACE OF COMPLIANCE.

(1) *For a Trial, Hearing, or Deposition.* A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

(A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or

(B) within the state where the person resides, is employed, or regularly transacts business in person, if the person

(i) is a party or a party's officer; or

(ii) is commanded to attend a trial and would not incur substantial expense.

(2) *For Other Discovery.* A subpoena may command:

(A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and

(B) inspection of premises at the premises to be inspected.

(d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.

(1) *Avoiding Undue Burden or Expense; Sanctions.* A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) *Command to Produce Materials or Permit Inspection.*

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) *Quashing or Modifying a Subpoena.*

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(e) DUTIES IN RESPONDING TO A SUBPOENA.

(1) *Producing Documents or Electronically Stored Information.* These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) *Claiming Privilege or Protection.*

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

(i) expressly make the claim; and

(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) CONTEMPT. The court for the district where compliance is required — and also, after a motion is transferred, the issuing court — may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

SCHEDULE A

A. Definitions

1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).

2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.

3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.

4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.

5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

6. "FDA" means the United States Food & Drug Administration.

7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.

8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.

9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.

10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.

11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.

12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).

13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

DOCUMENT TO BE PRODUCED

Corporate Organization

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

Contracts

1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.
3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

Communications with Relevant Parties

1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
    a. Date
    b. Recipients and/or Senders of the Communication
    c. General Subject Matter
    d. Basis of Privilege

ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

Nitrosamine Contamination

1. All communications between you and any Defendant relating to nitrosamines.
2. All communications between you and any Defendant concerning any toxicology assessment.
3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
6. All draft reports edited by you for comment and provided to any Defendant.
7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
10. All documents or communications relating to nitrosamine testing of any drug.

Recall-Related Documents

1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

Quarantine and/or Destruction

1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
5. All destruction certifications created related to any ARB products or API.

Communications with the FDA

1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

Testing Data

1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

Toxicology Assessments

1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION	No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: Envoy Health Care LLC, 800 Concourse Parkway South, Suite 200, Maitland, FL 32751.

Production: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Place:	Date and Time:
GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55401	November 15, 2020

Inspection of Premises: YOU ARE COMMANDED to permit entry onto the designated premises, land or other property possessed or controlled by you at the time, date and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property of any designated object or operation on it.

Place:	Date and Time:

The following provisions of Fed. R. Civ. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to you duty to respond to this subpoena and the potential consequences of not doing so.

Date: 10/15/2020

CLERK OF COURT

OR

_____ /s/ Marlene J. Goldenberg

Signature of Clerk or Deputy Clerk *Attorney's signature*

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:
Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, mjgoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

RELEVANT PORTIONS OF FED. R. CIV. P. 45

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3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.

4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.

5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

6. "FDA" means the United States Food & Drug Administration.

7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.

8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.

9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.

10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.

11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.

12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).

13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

DOCUMENT TO BE PRODUCED

Corporate Organization

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

Contracts

1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.
3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

Communications with Relevant Parties

1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
    a. Date
    b. Recipients and/or Senders of the Communication
    c. General Subject Matter
    d. Basis of Privilege

ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

Nitrosamine Contamination

1. All communications between you and any Defendant relating to nitrosamines.
2. All communications between you and any Defendant concerning any toxicology assessment.
3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
6. All draft reports edited by you for comment and provided to any Defendant.
7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
10. All documents or communications relating to nitrosamine testing of any drug.

Recall-Related Documents

1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

Quarantine and/or Destruction

1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
5. All destruction certifications created related to any ARB products or API.

Communications with the FDA

1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

Testing Data

1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

Toxicology Assessments

1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION	No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: Jost Chemical Co., 8150 Lackland Rd., St. Louis, MO 63114.

Production: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Place:	Date and Time:
GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55401	November 15, 2020

Inspection of Premises: YOU ARE COMMANDED to permit entry onto the designated premises, land or other property possessed or controlled by you at the time, date and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property of any designated object or operation on it.

Place:	Date and Time:

The following provisions of Fed. R. Civ. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to you duty to respond to this subpoena and the potential consequences of not doing so.

Date: 10/15/2020

CLERK OF COURT

OR

_____ /s/ Marlene J. Goldenberg

Signature of Clerk or Deputy Clerk *Attorney's signature*

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:
Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, mjgoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

RELEVANT PORTIONS OF FED. R. CIV. P. 45

(c) PLACE OF COMPLIANCE.

(1) *For a Trial, Hearing, or Deposition.* A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

(A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or

(B) within the state where the person resides, is employed, or regularly transacts business in person, if the person

(i) is a party or a party's officer; or

(ii) is commanded to attend a trial and would not incur substantial expense.

(2) *For Other Discovery.* A subpoena may command:

(A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and

(B) inspection of premises at the premises to be inspected.

(d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.

(1) *Avoiding Undue Burden or Expense; Sanctions.* A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) *Command to Produce Materials or Permit Inspection.*

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) *Quashing or Modifying a Subpoena.*

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(e) DUTIES IN RESPONDING TO A SUBPOENA.

(1) *Producing Documents or Electronically Stored Information.* These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) *Claiming Privilege or Protection.*

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

(i) expressly make the claim; and

(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) CONTEMPT. The court for the district where compliance is required — and also, after a motion is transferred, the issuing court — may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

SCHEDULE A

A. Definitions

1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).

2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.

3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.

4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.

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preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

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drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.
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6. All draft reports edited by you for comment and provided to any Defendant.
7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
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9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
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1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

Testing Data

1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

Toxicology Assessments

1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION	No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: Spectral Data Services Inc., 818 Pioneer Street, Champaign, IL 61820.

Production: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Place:	Date and Time:
GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55401	November 15, 2020

Inspection of Premises: YOU ARE COMMANDED to permit entry onto the designated premises, land or other property possessed or controlled by you at the time, date and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property of any designated object or operation on it.

Place:	Date and Time:

The following provisions of Fed. R. Civ. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to you duty to respond to this subpoena and the potential consequences of not doing so.

Date: 10/15/2020

CLERK OF COURT

OR

_____ /s/ Marlene J. Goldenberg

Signature of Clerk or Deputy Clerk *Attorney's signature*

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:
Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, mjgoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

RELEVANT PORTIONS OF FED. R. CIV. P. 45

(c) PLACE OF COMPLIANCE.

(1) *For a Trial, Hearing, or Deposition.* A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

(A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or

(B) within the state where the person resides, is employed, or regularly transacts business in person, if the person

(i) is a party or a party's officer; or

(ii) is commanded to attend a trial and would not incur substantial expense.

(2) *For Other Discovery.* A subpoena may command:

(A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and

(B) inspection of premises at the premises to be inspected.

(d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.

(1) *Avoiding Undue Burden or Expense; Sanctions.* A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) *Command to Produce Materials or Permit Inspection.*

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) *Quashing or Modifying a Subpoena.*

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(e) DUTIES IN RESPONDING TO A SUBPOENA.

(1) *Producing Documents or Electronically Stored Information.* These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) *Claiming Privilege or Protection.*

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

(i) expressly make the claim; and

(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) CONTEMPT. The court for the district where compliance is required — and also, after a motion is transferred, the issuing court — may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

SCHEDULE A

A. Definitions

1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).

2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.

3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.

4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.

5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

6. "FDA" means the United States Food & Drug Administration.

7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.

8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.

9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.

10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.

11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.

12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).

13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

DOCUMENT TO BE PRODUCED

Corporate Organization

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

Contracts

1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.
3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

Communications with Relevant Parties

1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
    a. Date
    b. Recipients and/or Senders of the Communication
    c. General Subject Matter
    d. Basis of Privilege

ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

Nitrosamine Contamination

1. All communications between you and any Defendant relating to nitrosamines.
2. All communications between you and any Defendant concerning any toxicology assessment.
3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
6. All draft reports edited by you for comment and provided to any Defendant.
7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
10. All documents or communications relating to nitrosamine testing of any drug.

Recall-Related Documents

1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

Quarantine and/or Destruction

1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
5. All destruction certifications created related to any ARB products or API.

Communications with the FDA

1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

Testing Data

1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

Toxicology Assessments

1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION	No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: Chemir Pharma Services, 2672 Metro Blvd., Maryland Heights, MO 63043.

Production: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Place:	Date and Time:
GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55401	November 15, 2020

Inspection of Premises: YOU ARE COMMANDED to permit entry onto the designated premises, land or other property possessed or controlled by you at the time, date and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property of any designated object or operation on it.

Place:	Date and Time:

The following provisions of Fed. R. Civ. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to you duty to respond to this subpoena and the potential consequences of not doing so.

Date: 10/15/2020

CLERK OF COURT

OR

_____ /s/ Marlene J. Goldenberg

Signature of Clerk or Deputy Clerk *Attorney's signature*

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:
Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, mjgoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

RELEVANT PORTIONS OF FED. R. CIV. P. 45

(c) PLACE OF COMPLIANCE.

(1) *For a Trial, Hearing, or Deposition.* A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

(A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or

(B) within the state where the person resides, is employed, or regularly transacts business in person, if the person

(i) is a party or a party's officer; or

(ii) is commanded to attend a trial and would not incur substantial expense.

(2) *For Other Discovery.* A subpoena may command:

(A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and

(B) inspection of premises at the premises to be inspected.

(d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.

(1) *Avoiding Undue Burden or Expense; Sanctions.* A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) *Command to Produce Materials or Permit Inspection.*

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) *Quashing or Modifying a Subpoena.*

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(e) DUTIES IN RESPONDING TO A SUBPOENA.

(1) *Producing Documents or Electronically Stored Information.* These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) *Claiming Privilege or Protection.*

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

(i) expressly make the claim; and

(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) CONTEMPT. The court for the district where compliance is required — and also, after a motion is transferred, the issuing court — may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

SCHEDULE A

A. Definitions

1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).

2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.

3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.

4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.

5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

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8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.

9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.

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DOCUMENT TO BE PRODUCED

Corporate Organization

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

Contracts

1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.
3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

Communications with Relevant Parties

1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
    a. Date
    b. Recipients and/or Senders of the Communication
    c. General Subject Matter
    d. Basis of Privilege

ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

Nitrosamine Contamination

1. All communications between you and any Defendant relating to nitrosamines.
2. All communications between you and any Defendant concerning any toxicology assessment.
3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
6. All draft reports edited by you for comment and provided to any Defendant.
7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
10. All documents or communications relating to nitrosamine testing of any drug.

Recall-Related Documents

1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

Quarantine and/or Destruction

1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
5. All destruction certifications created related to any ARB products or API.

Communications with the FDA

1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

Testing Data

1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

Toxicology Assessments

1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION	No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: Ratiopharm, Graf-Arco-Strasse 3 Ulm, D-89079 Germany.

Production: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Place:	Date and Time:
GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55401	November 15, 2020

Inspection of Premises: YOU ARE COMMANDED to permit entry onto the designated premises, land or other property possessed or controlled by you at the time, date and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property of any designated object or operation on it.

Place:	Date and Time:

The following provisions of Fed. R. Civ. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to you duty to respond to this subpoena and the potential consequences of not doing so.

Date: _____

CLERK OF COURT

OR

_____ _____

Signature of Clerk or Deputy Clerk *Attorney's signature*

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, mjgoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

RELEVANT PORTIONS OF FED. R. CIV. P. 45

(c) PLACE OF COMPLIANCE.

(1) *For a Trial, Hearing, or Deposition.* A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

(A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or

(B) within the state where the person resides, is employed, or regularly transacts business in person, if the person

(i) is a party or a party's officer; or

(ii) is commanded to attend a trial and would not incur substantial expense.

(2) *For Other Discovery.* A subpoena may command:

(A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and

(B) inspection of premises at the premises to be inspected.

(d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.

(1) *Avoiding Undue Burden or Expense; Sanctions.* A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) *Command to Produce Materials or Permit Inspection.*

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) *Quashing or Modifying a Subpoena.*

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(e) DUTIES IN RESPONDING TO A SUBPOENA.

(1) *Producing Documents or Electronically Stored Information.* These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

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    a. Date
    b. Recipients and/or Senders of the Communication
    c. General Subject Matter
    d. Basis of Privilege

ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

Nitrosamine Contamination

1. All communications between you and any Defendant relating to nitrosamines.
2. All communications between you and any Defendant concerning any toxicology assessment.
3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
6. All draft reports edited by you for comment and provided to any Defendant.
7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
10. All documents or communications relating to nitrosamine testing of any drug.

Recall-Related Documents

1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

Quarantine and/or Destruction

1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
5. All destruction certifications created related to any ARB products or API.

Communications with the FDA

1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

Testing Data

1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

Toxicology Assessments

1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION	No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: MSN Laboratories Pvt. Ltd., MSN House, Plot No C-24 Industrial Estate, Sanathnagar Hyderabad, 500018 India.

Production: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Place:	Date and Time:
GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55401	November 15, 2020

Inspection of Premises: YOU ARE COMMANDED to permit entry onto the designated premises, land or other property possessed or controlled by you at the time, date and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property of any designated object or operation on it.

Place:	Date and Time:

The following provisions of Fed. R. Civ. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to you duty to respond to this subpoena and the potential consequences of not doing so.

Date: _____

CLERK OF COURT

OR

_____ _____

Signature of Clerk or Deputy Clerk *Attorney's signature*

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, mjgoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

RELEVANT PORTIONS OF FED. R. CIV. P. 45

(c) PLACE OF COMPLIANCE.

(1) *For a Trial, Hearing, or Deposition.* A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

(A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or

(B) within the state where the person resides, is employed, or regularly transacts business in person, if the person

(i) is a party or a party's officer; or

(ii) is commanded to attend a trial and would not incur substantial expense.

(2) *For Other Discovery.* A subpoena may command:

(A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and

(B) inspection of premises at the premises to be inspected.

(d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.

(1) *Avoiding Undue Burden or Expense; Sanctions.* A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) *Command to Produce Materials or Permit Inspection.*

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) *Quashing or Modifying a Subpoena.*

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(e) DUTIES IN RESPONDING TO A SUBPOENA.

(1) *Producing Documents or Electronically Stored Information.* These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) *Claiming Privilege or Protection.*

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

(i) expressly make the claim; and

(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) CONTEMPT. The court for the district where compliance is required — and also, after a motion is transferred, the issuing court — may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

SCHEDULE A

A. Definitions

1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).

2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.

3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.

4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.

5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

6. "FDA" means the United States Food & Drug Administration.

7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.

8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.

9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.

10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.

11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.

12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).

13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

DOCUMENT TO BE PRODUCED

Corporate Organization

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

Contracts

1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.
3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

Communications with Relevant Parties

1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
    a. Date
    b. Recipients and/or Senders of the Communication
    c. General Subject Matter
    d. Basis of Privilege

ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

Nitrosamine Contamination

1. All communications between you and any Defendant relating to nitrosamines.
2. All communications between you and any Defendant concerning any toxicology assessment.
3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
6. All draft reports edited by you for comment and provided to any Defendant.
7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
10. All documents or communications relating to nitrosamine testing of any drug.

Recall-Related Documents

1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

Quarantine and/or Destruction

1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
5. All destruction certifications created related to any ARB products or API.

Communications with the FDA

1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

Testing Data

1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

Toxicology Assessments

1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION	No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

To: Cobalt Pharmaceuticals Inc., 6733 Mississauga Rd., Suite 400 Mississauga, L5N 6J5 Canada.

Production: YOU ARE COMMANDED to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See attached Schedule A

Place:	Date and Time:
GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55401	November 15, 2020

Inspection of Premises: YOU ARE COMMANDED to permit entry onto the designated premises, land or other property possessed or controlled by you at the time, date and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property of any designated object or operation on it.

Place:	Date and Time:

The following provisions of Fed. R. Civ. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to you duty to respond to this subpoena and the potential consequences of not doing so.

Date: _____

CLERK OF COURT

OR

_____ _____

Signature of Clerk or Deputy Clerk *Attorney's signature*

The name, address, e-mail address, and telephone number of the attorney representing the Plaintiffs, who have issued the requests or subpoena are:

Marlene J. Goldenberg, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402, mjgoldenberg@goldenberglaw.com; scheriff@goldenberglaw.com (legal assistant); valsartan@csdisco.com (ESI Vendor).

RELEVANT PORTIONS OF FED. R. CIV. P. 45

(c) PLACE OF COMPLIANCE.

(1) *For a Trial, Hearing, or Deposition.* A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

(A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or

(B) within the state where the person resides, is employed, or regularly transacts business in person, if the person

(i) is a party or a party's officer; or

(ii) is commanded to attend a trial and would not incur substantial expense.

(2) *For Other Discovery.* A subpoena may command:

(A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and

(B) inspection of premises at the premises to be inspected.

(d) PROTECTING A PERSON SUBJECT TO A SUBPOENA; ENFORCEMENT.

(1) *Avoiding Undue Burden or Expense; Sanctions.* A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) *Command to Produce Materials or Permit Inspection.*

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) *Quashing or Modifying a Subpoena.*

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(e) DUTIES IN RESPONDING TO A SUBPOENA.

(1) *Producing Documents or Electronically Stored Information.* These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) *Claiming Privilege or Protection.*

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

(i) expressly make the claim; and

(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) CONTEMPT. The court for the district where compliance is required — and also, after a motion is transferred, the issuing court — may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

SCHEDULE A

A. Definitions

1. "Action" means the above-captioned lawsuit: *In re: Valsartan, Losartan and Irbesartan Products Liability Litigation*, MDL No. 2875 (District of New Jersey).

2. "Communication" means the transmittal of information or a request for information (in the form of facts, ideas, inquiries, or otherwise), whether by written, oral, electronic, or other means. Communications include, but are not limited to all discussions, conversations, meetings, conferences, telephone conversations, interviews, voicemails, negotiations, agreements, understandings, letters, correspondence, facsimiles, electronic mail, or other forms of written or verbal interchanges, however transmitted or stored, including reports, notes, memoranda, lists, chats or instant messages, agendas and other records of communications.

3. "Concern," "Concerning," or "Relating to" means referring to, relating to, describing, evidencing, constituting, pertaining to, containing, describing, embodying, mentioning, supporting, corroborating, demonstrating, proving, evidencing, showing, refuting, disputing, rebutting, controverting, contradicting, or relating to.

4. "You" or "Your" means the answering party, its employees, agents, and officers and any affiliated entity of the answering party to whom this Subpoena is directed.

5. "Documents" includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation, whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof. This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term "Document" includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form), and any

preliminary versions, drafts or revisions of any of the foregoing and shall also include electronic communications, whether maintained presently in the normal course of business or available in back-up or legacy data formats, wherever found or maintained, including all servers, hard drives, thumb drives, palms, blackberries, cell phones, laptops and firewalls. Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. "Documents" also includes the content of any applicable computer database.

6. "FDA" means the United States Food & Drug Administration.

7. "Sartan" or "ARB" includes the three Angiotensin II Receptor Blockers (ARBs) which have been included within MDL 2875, specifically the drugs: (1) valsartan, (2) losartan, and (3) Irbesartan. Valsartan means any drug with valsartan as an active ingredient and also includes the API for valsartan on its own, as well as all finished drug formulations of valsartan, including any valsartan containing drug. Losartan means any drug with losartan as an active ingredient and also includes the API for losartan on its own, as well as all finished drug formulations of losartan, including any losartan containing drug. Irbesartan means any drug with irbesartan as an active ingredient and also includes the API for irbesartan on its own, as well as all finished drug formulations of irbesartan, including any Irbesartan containing drug. These three ARBs shall be referred to collectively herein as the "Sartan" products.

8. "Recalled Products" means those Valsartan, Losartan, and Irbesartan drug products that have been recalled by the FDA.

9. "Active Pharmaceutical Ingredient" ("API") means any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.

10. Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is September 1, 2012 to the present.

11. "Regulatory and Regulatory Authority" refers to United States and foreign regulatory agencies.

12. "API Manufacturer" is defined as any entity that manufactures active pharmaceutical ingredients (APIs).

13. "Finished Dose Manufacturer" includes any entity that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating,

compounding, processing, packaging, repackaging, or labeling of valsartan. The term "finished dose manufacturer" also includes entities who hold ANDAs.

14. "Defendants" means all Defendants who have been named within MDL 2875, including but not limited to: Aurobindo Pharma, Ltd.; Hetero Drugs, Ltd.; Hetero Labs, Ltd.; Mylan Laboratories, Ltd.; Mylan N.V.; Zhejiang Huahai Pharmaceutical Co. Ltd.; Arrow Pharma (Malta) Ltd.; Aurolife Pharma, LLC; Mylan Pharmaceuticals Inc.; Teva Pharmaceutical Industries, Ltd.; Torrent Pharmaceuticals, Ltd.; Hetero USA, Inc.; Prinston Pharmaceutical Inc.; Aceteris, LLC; Actavis, LLC; Actavis Pharma Inc.; A-S Medication Solutions, LLC; Aurobindo Pharma USA, Inc.; AvKARE, Inc.; Bryant Ranch Prepack, Inc.; Camber Pharmaceuticals, Inc.; Cardinal Heatlh; The Harvard Drug Group, LLC d/b/a Major Pharmaceuticals; HJ Harkins Co, Inc.; Huahai U.S. Inc.; Northwind Pharmaceuticals; NuCare Pharmaceuticals, Inc.; Preferred Pharmaceuticals, Inc.; Remedy Repack, Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Torrent Pharma, Inc.; Amerisource Bergen Corporation; Cardinal Health, Inc.; McKesson Corporation; Albertson's Companies, LLC; Cigna Corporation; CVS Health; Express Scripts, Inc.; Humana Pharmacy, Inc.; The Kroger Co.; Optum Rx; Optum, Inc.; Rite Aid Corp.; Walgreens Boots Alliance; and Wal-Mart, Inc.

DOCUMENT TO BE PRODUCED

Corporate Organization

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

Contracts

1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.
2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB

drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.
3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

Communications with Relevant Parties

1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.
2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:
    a. Date
    b. Recipients and/or Senders of the Communication
    c. General Subject Matter
    d. Basis of Privilege

ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

Nitrosamine Contamination

1. All communications between you and any Defendant relating to nitrosamines.
2. All communications between you and any Defendant concerning any toxicology assessment.
3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.
4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.
5. All reports and/or draft reports provided to you regarding the nitrosamine investigation
6. All draft reports edited by you for comment and provided to any Defendant.
7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.
8. All testing protocols used by you to test for the presence of nitrosamines in any drug.
9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.
10. All documents or communications relating to nitrosamine testing of any drug.

Recall-Related Documents

1. All documents relating to the decision on whether to recall or not to recall any ARBs API.
2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.
3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

Quarantine and/or Destruction

1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.
2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.
3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.
4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.
5. All destruction certifications created related to any ARB products or API.

Communications with the FDA

1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.
2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.
3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.
4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.
5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.
6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

Testing Data

1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.
2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.
3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.
4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.
2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.
5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.
6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

Toxicology Assessments

1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.
2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API
3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.
4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.